IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

HOPE HUERTA as Next Friend and Parent of BLANCA M. VALDEZ-HUERTA, a minor,

Plaintiffs,

vs. Civ. No. 09-485 RHS/LFG

BIOSCRIP PHARMACY SERVICES, INC., and DOES 1-25,

Defendants.

MEMORANDUM OPINION AND ORDER

THIS MATTER is before the Court on Defendant BioScrip Pharmacy Services Inc.'s *Daubert Motion to Exclude Certain Proposed Testimony of Craig Wong, M.D., Bruce Morgenstern, M.D., and Loyd Alexander, M.D.*, filed May 12, 2010 [Doc. 175]. The parties have not requested a hearing. Having considered the parties' submissions and the relevant law, the Court concludes that the motion should be granted as set forth below.[1]

I. Legal Standards.

Under Federal Rule of Civil Procedure 702:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

[1] Pursuant to 28 U.S.C. § 636(c) and FED. R. CIV. P. 73(b), the parties have consented to have me serve as the presiding judge and enter final judgment. *See* Docs. 8, 25.

The "overarching subject [of an inquiry under Rule 702] is the scientific validity—and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission." *Daubert v. Merrill Dow Pharm.*, 509 U.S. 590, 594 (1993)

> . . . . The subject of an expert's testimony must be "scientific [, technical, or other specialized] knowledge." The adjective " scientific" implies a grounding in the methods and procedures of science. Similarly, the word "knowledge" connotes more than subjective belief or unsupported speculation. The term "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds." Webster's Third New International Dictionary 1252 (1986). Of course, it would be unreasonable to conclude that the subject of scientific testimony must be "known" to a certainty; arguably, there are no certainties in science. . . . Instead, it represents a process for proposing and refining theoretical explanations about the world that are subject to further testing and refinement (emphasis in original)). But, in order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation- *i.e.*, "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.
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> . . . .[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation. *See* Rules 702 and 703. Presumably, this relaxation of the usual requirement of firsthand knowledge-a rule which represents "a 'most pervasive manifestation' of the common law insistence upon 'the most reliable sources of information,' " Advisory Committee's Notes on Fed. Rule Evid. 602, 28 U.S.C. App., p. 755 (citation omitted)-is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.
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> Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589-93 (1993) (footnotes omitted). Thus, "[a]n expert, no matter how good his credentials, is not permitted to speculate." *Goebel v. Denver & Rio Grande W. R.R. Co.*, 215 F.3d 1083, 1088 (10th Cir. 2000). "[T]he factors identified in

Daubert may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999). "The objective of [*Daubert's* gatekeeping] requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.

II. Background facts.

In 2003, seven-year-old Blanca Valdez-Huerta received a kidney transplant. Thereafter, she took numerous medications, including tacrolimus and Cellcept, to suppress her immune system and help prevent rejection of the implant. In the spring of 2006, BioScrip compounded from capsules, and dispensed as a liquid suspension, the prescribed tacrolimus that Blanca orally ingested. It is undisputed that, in 2006, BioScrip used a capsulated form of tacrolimus manufactured and distributed by Astellas Pharma U.S. Inc. ("Astellas") to compound its tacrolimus suspension. The Plaintiffs voluntarily dismissed Astellas as a Defendant because there was no evidence that the tacrolimus Astellas manufactured and supplied to BioScrip was subpotent or had been the subject of any recall. *See* Doc. 39. And the Plaintiffs have produced no direct evidence, from testing the suspension Blanca ingested or examining the compounding records, for example, that BioScrips' April or May 2006 formulations were, in fact, subpotent or improperly compounded.

Blanca was hospitalized in February 2006 after a "series of pneumonias that didn't clear with antibiotics." Doc. 175, Ex. B at 6. On March 8, 2006, Dr. John Brandt and other treating nephrologists substituted Imuran for the Cellcept. *See id.* at 5. Blanca had been taking Cellcept since the implant, but her doctors took her off of it because they thought the Cellcept was

"oversuppressing [production] of white blood cells . . . that may have led to an increased risk of infection." Doc. 201, Ex. 3 at 3 (Dr. John Brandt's Depo.); Doc. 175, Ex. C at 12 (Dr. Alexander's deposition, stating that a "low white blood cell count . . . [is] the most common side effect of CellCept."). Imuran is also an immunosuppressant that "suppresses the immune system less" than Cellcept. Doc. 181, Ex. 2 at 6 (Dr. Wong's Depo.).

In May 2006 Blanca experienced a severe, acute rejection of her transplanted kidney[2]. When she was admitted to the hospital the afternoon of May 15, 2006, she had been vomiting "one to two times per night" for three nights, and she continued to vomit through May 16. *See* Doc. 175, Ex. B at 5-6. Dr. Brandt reduced Blanca's prescription of tacrolimus on May 15 because he was concerned that she might have too much tacrolimus in her system. *See id.* at 6. There was no way to know what Blanca's tacrolimus levels were on May 15 because no "level was drawn on that day." *Id.* On May 17, 2006, laboratory reports showed a tacrolimus level of 2.5 in Blanca's system. *See* Doc. 198, Ex. A at 2. No laboratory testing of Blanca's tacrolimus levels had been performed before May 15 except for her monthly testing on April 12, which was apparently normal at 5.4. *See id.* The basis of the Plaintiffs' lawsuit, however, is that, as a result of Blanca's ingestion of BioScrip's allegedly subpotent tacrolimus, she rejected her transplanted kidney in May 2006.

III. Dr. Wong's testimony.

Dr. Wong is one of Blanca's treating nephrologists who will also be testifying as an expert. Although he expressed his opinion that "[k]idney transplants do go to failure despite excellent care

[2] Blanca partially recovered from this rejection, but suffered another acute rejection in 2007 and had to undergo a second transplant.

and immunosuppression for mechanisms that are not completely understood,[3]" Doc. 175, Ex. B at 3, he testified that he saw "evidence that [Blanca's] immune system had mounted a significant attack on her kidney transplant," in May 2006, which is caused when one does not have sufficient "medications to block the immune system." Doc. 181, Ex. 1 at 3. Dr. Wong testified that dehydration may impact tacrolimus absorption if "you've got kidney failure;" that "there can be interactions with antibiotics;" and that "vomiting can impact absorption rates of tacrolimus." Doc. 175, Ex. B at 4-5. Dr. Wong testified that it was "possible" that the vomiting she experienced had affected Blanca's absorption of tacrolimus and that he could not say, to a "reasonable degree of medical probability" that the vomiting had *not* compromised Blanca's tacrolimus levels because "without the level, there is no way to know." *Id.* at 6.

Things that could cause a severe gap in getting immunosuppressants include "not taking" the immunosuppressant medications; "taking it and not having the proper drug," as when the child is getting someone else's prescription by mistake; and "discontinuation of medications." Doc. 198, Ex. A at 4. Dr. Wong testified that, because Blanca had been doing well before she was admitted to the hospital on May 15, "we had no reason to believe that, at that time, there was any noncompliance." Doc. 181, Ex. 1 at 4. Dr. Wong testified that he and Dr. Alexander, another of Blanca's treating nephrologists in California, "conjectured . . . after seeing the [recall] report," Doc. 181, Ex. 2 at 5, and he arrived at a "hypothesis" that subpotent medication "most likely was the cause" of Blanca's insufficient tacrolimus levels and her subsequent rejection for two reasons: (1) he heard about a recall of tacrolimus that was subpotent and the "timing of it correlated very well . . . and the severity of the rejection seemed to fit;" and (2) Dr. Alexander told him that "other

[3] Dr. Alexander also agreed with this statement. *See* Doc. 175, Ex. C at 14.

children who had liquid preparations of [tacrolimus] had undetectable levels of [tacrolimus] even though they were very compliant." *Id.* Ex. 1 at 4-5. He did not know "which brand or which company" had issued the recall, Doc. 181, Ex. 2 at 4, but his mindset in 2006 and 2007 was that, because of the severity of Blanca's rejection and the recall, he assigned a "blanket blame on every liquid [tacrolimus] preparation and, you know, guilty unless proven innocent." Doc. 175, Ex. B. at 10.

As it turned out, however, as mentioned above, a different manufacturer, and not BioScrip's supplier, recalled its tacrolimus preparations that were based on powdered tacrolimus, and the recall specifically did not apply to the "finished dosage form" tacrolimus capsules that BioScrip "used for compounding." *Id.* at 4. Thus, Dr. Wong had nothing with which to "test" his hypothesis. *See* Doc. 181, Ex. 1 at 5. He conceded that, "we have to test the hypothesis. So unless we can test it and establish what was going on, it's hard to say without any documented [tacrolimus] levels on the 16th. It's guesswork." Doc. 175, Ex. B at 10. When Blanca's tacrolimus levels dropped to 4.5 in August 2006 while she was taking tacrolimus capsules instead of BioScrip's suspension, Dr. Wong thought that the low level could "be a timing thing" *i.e.*, that the blood level may have been drawn during a "trough" twelve hours after her previous dose[4], or that it may have been affected by hydration. *See id.* at 8. Nevertheless, Dr. Wong testified that, based on the fact that he had *no* direct evidence to show that the tacrolimus BioScrip dispensed to Blanca was in fact at its "appropriate concentration," he believed *in May 2007*, to a "reasonable degree of medical probability" that "Blanca had subpotent medications, that had led towards her rejection, unless there is evidence that shows otherwise." Doc. 181, Ex. 1 at 6-7 (stating that this opinion was "based on the fact that [he]

[4] Dr. Tackett testified that the lowest blood level of tacrolimus will be demonstrated if it is taken at the "trough" or end, of the 12-hour dosing period. *See* Doc. 174, Ex. A. at 7.

believed at the time [he] gave that testimony, that there were test results showing that the medication was subpotent . . . .”). Dr. Wong’s final testimony on May 4, 2010 is that, if there is “no evidence to show that [BioScrip’s compounded tacrolimus suspension given to Blanca] was subpotent, then I don’t think anybody can say what caused the rejection, and that’s just history.” Doc. 203, Ex. 1 at 9[5]. When asked if he could rule out other reasons for lapses in Blanca’s immunosuppressant therapy, he stated, “unless we have evidence to support any of those, we just know that the rejection happened. . . . .[W]e can guess for a long time what might have caused it.” *Id.* at 10.

IV. Dr. Alexander’s testimony.

Dr. Alexander was involved with the 2003 transplant and then treated Blanca in California for a period of time after the May 2006 rejection episode. He states that Blanca’s attorneys told him that the tacrolimus suspension BioScrip dispensed to Blanca prior to her May 2006 rejection “was inadequate,” and that references in his medical records to the tacrolimus being “thought to be subpotent” came from conversations with Dr. Wong and Dr. Brandt involving “hypotheticals” about what could have caused her severe rejection. Doc. 175, Ex. C at 2, 4-5. He stated that, “there is almost nothing that will basically have the kidney go from .6 to a creatinine of 9, except nonadherence.” *Id.* at 8. He also stated that, “if Imuran is inadequate in combination with the [tacrolimus] to prevent rejection, then you could see rejection from a change from [tacrolimus]/Cellcept to [tacrolimus]/Imuran.” *Id.* at 9. He further acknowledged that malabsorption caused by vomiting can “cause [tacrolimus] levels to drop.” *Id.* at 10-11. He believes, however, that “the severity of “Blanca’s] rejection and the kidney failure was too rapid to

[5] Although the parties did not attach these pages to their briefing on BioScrip’s *Daubert* motion, the Court has read all of the deposition testimony of all of the challenged physicians that has been placed into the record in an attempt to make sure that the Court correctly resolves the issues related to its duty as a “gatekeeper” of expert testimony that may go to the jury.

have happened in that short period of time" when she was vomiting before she came to the hospital. *Id.* at 11.

Dr. Alexander agreed that, if the person administering tacrolimus suspension fails to shake the bottle before measuring out the dose, "you can have low [tacrolimus] concentrations in the liquid that you start the month out with. And then you can also have it because of a formulation error." *Id.* at 13. Dr. Alexander is expected to testify, however, that, to a reasonable degree of medical probability, Blanca's rejection was caused by "inadequate immunosuppression," and that the inadequacy was caused by "a preparation of tacrolimus that was insufficient," because, based on "knowing" Blanca's family, he had ruled out nonadherence in taking the tacrolimus, which would be the other most likely reason for inadequate immunosuppression. *Id.* at 14-15.

When he gave that opinion, however, Dr. Alexander was unaware of Dr. Brandt's testimony that, in 2007, Blanca was again "admitted for undetectable levels of [t]acrolimus in her system,"[6] and that Dr. Brandt expressed concern that "multiple family members were providing Blanca with her oral medications, and that . . . she wasn't being dosed sufficiently" because, when she was admitted to the hospital "and the hospital began providing her medications to her [], her [t]acrolimus levels stabilized."[7] *Id.* at 16-17.

V. Dr. Morganstern's testimony.

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[6] Dr. Wong testified that, in May 2007, Blanca's medical records showed that "she had undetectable levels" of tacrolimus and that the doctors were concerned "that her mother wasn't dosing her properly." Doc. 181, Ex. 2 at 3.

[7] According to the medical records, in May 2007 Dr. Brandt reported: "In the past 2 weeks Blanca has had difficulty with achieving adequate blood levels of Rapamycin and [tacrolimus]. During this time multiple family members have been responsible for medication administration and we suspect this has been inadequate. Here in the hospital on her standard medication doses, her [tacrolimus] level was most recently 8.7 and a Rapamycin level 5.8." Doc. 175, Ex. D at 6.

The Plaintiffs' expert, Dr. Bruce Morganstern noted that dehydration, antibiotic medications, vomiting, and lack of compliance all could "affect a patient's tacrolimus levels." Doc. 175, Ex. D at 2. He stated, however, that "all other likely etiologies for low levels [of tacrolimus] had been ruled out," based on information he received from the treating physicians in the medical records regarding her May 2006 admission and rejection. Critically, Dr. Morganstern commented that Dr. Alexander's medical notes "categorical[ly]" "say that the patient had a rejection episode due to subpotent tacrolimus," *id.* at 5, "leading [Dr. Morgenstern] to believe that somehow they'd established that fact. It's not something . . . that you enter in the medical record unless you know it," *id.* at 6. And part of his belief that other likely etiologies had been ruled out was based on an *absence* of information in the medical records. For example, he states that, if Blanca's doctors "thought . . . there was nonadherence on the part of the parent to administer the medication," or that the vomiting "contributed to the low levels and was the proximate cause of the low levels," "they would have said that" in the record. *Id.* at 4.

Dr. Morganstern acknowledges that there was "no way" to know Blanca's tacrolimus level before she started vomiting and that vomiting can "contribute" to a low tacrolimus level. He believes, however, that because of her high creatinine levels on May 15, the fact that her creatinine levels had been fine a month previously, and the severe nature of the rejection, the vomiting was caused from renal failure. *See id.* at 3. And he stated that, even though Dr. Brandt had lowered Blanca's dosage of tacrolimus by more than half on May 15, thereby making it a "potential explanation" for her low tacrolimus levels on May 17, based on her "acute cellular rejection and humeral rejection and a creatinine of 9.1, the medical probability is that her levels were low prior to that." *Id.* Based on this information and information and/or lack of information from other doctors, Dr. Morganstern is expected to testify at trial that it was "highly probable" that the reason

for Blanca's low levels in May 2006 was the subpotency of BioScrip's tacrolimus suspension. *Id.* at 2; *see id.* at 4.

Although he was aware that in May 2007 Blanca again experienced high creatinine levels and undetectable levels of tacrolimus in her blood and he had been unable to determine why from the records, he was *unaware* that "Dr. Brandt was concerned about compliance of the family in the dosing of the tacrolimus." *Id.* at 6. Dr. Morganstern agreed that doctors do not "always know when [their] patients are complying with their medication," and that it was "possible" that Dr. Brandt and Dr. Wong "just didn't know that there were compliance issues in May of 2006." *Id.*

VI. Analysis.

BioScrip admits, and the Court agrees, that, Dr. Wong, Dr. Alexander, and Dr. Morganstern all are qualified to give expert opinions about what conditions *may* cause a transplant rejection. They also are all well qualified to give an opinion stating that, based on (1) the severity (2) the type, and (3) abruptness of Blanca's rejection when she had been doing well the month before, (4) the extremely high creatinine levels in her blood on May 15, 2006, and the fact that (5) tacrolimus is the most powerful and the most critical immunosuppressant medication Blanca was taking (which all are medical facts well supported in the medical record and medical literature), Blanca's rejection was most likely caused by insufficient levels of tacrolimus and/or other immunosuppressants in her system.

What is *not* supported by any medical evidence in the record, however, are their opinions regarding the *cause of the insufficient tacrolimus level*. First, Dr. Wong's and Dr. Alexander's factual assumption, *based on the recall*, that BioScrip's tacrolimus suspension was subpotent or inadequate was totally erroneous because BioScrip's suspension was not compounded from the recalled tacrolimus powder. As mentioned, *supra*, there is no direct evidence to show that

BioScrip's suspension was subpotent or inadequate in any way, although it would have been easy enough for the doctors or the Plaintiffs to have tested it.

An opinion that is derived from erroneous facts or assumptions is not reliable because it is not "supported by appropriate validation-*i.e.*, 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590; *see* FED. R. EVID. 702 (requiring expert testimony to be based on "sufficient facts or data" and the "product of reliable principles and methods"); *cf. Orth v. Emerson Elec. Co., White-Rodgers Div.*, 980 F.2d 632, 637 (10th Cir. 1992) (affirming court's decision to admit testimony that "served to 'connect up' the direct evidence" and noting that an expert may make assumptions if they are based on "known facts, together with his experience and knowledge of causation factors, and drawing a rational conclusion as to causation"). Neither Dr. Wong's nor Dr. Alexander's opinions purporting to place the cause of Blanca's insufficient immunosuppression in May 2006 on subpotent or inadequate tacrolimus suspension is reliable because each is based on an erroneous assumption and is not based on any known facts. And because Dr. Morganstern's opinion regarding the causation of insufficient tacrolimus levels is based on Dr. Wong's and Dr. Alexander's notations in the medical record regarding allegedly subpotent tacrolimus and his false assumption that Dr. Alexander had already categorically established that the tacrolimus suspension was "subpotent," Dr. Morganstern's ultimate-causation opinion also is not reliable, and is, therefore, inadmissible.

There are other difficulties with the experts' ultimate-causation opinions. Insofar as the Plaintiffs' experts may be attempting to establish causation using the "differential diagnosis method,"[8] their attempts fall far short. As Dr. Alexander noted, "almost nothing [] will have the

[8] "'Differential diagnosis' refers to the process by which a physician 'rules in' all scientifically plausible causes of the plaintiff's injury.

kidney go from .6 to a creatnine of 9, except nonadherence" in taking immunosuppressant medications. Doc. 175, Ex. C at 8; *see also* Doc. 17, Ex. A at 7 (Dr. Wong's deposition testimony stating that he had "hardly seen any severe acute rejections except for the cellular ones where the teens stopped taking their medicines . . . for like a month."). But Dr. Alexander and Dr. Wong apparently summarily ruled out nonadherence based only on "knowing" Blanca's family. Nothing in the record or the depositions excerpts provided by the parties indicates that any of Blanca's treating physicians actually investigated in 2006 whether Blanca's family had, in fact, properly dosed her during the weeks before the rejection or that they had examined the suspension bottles to determine how much of the suspension had been used. And neither Dr. Alexander nor Dr. Morganstern were aware of the medical records showing Blanca's subsequent incident, only a year later – when Blanca took a different form of tacrolimus – of "undetectable" blood levels of both of her immunosuppressants, which was corrected upon her hospitalization and administration of the medications by hospital staff. As Dr. Morganstern agreed, Blanca's doctors may simply have been unaware of similar dosing issues in May of 2006 and never thought of ruling them out. The Court

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> The physician then 'rules out' the least plausible causes of injury until the most likely cause remains. The remaining cause is the expert's conclusion." *Hollander* [*v. Sandoz Pharm. Corp.*], 289 F.3d [1193], 1209 [(10th Cir. 2002)],(citation and quotation omitted). We have emphasized that the remaining cause must have been "ruled in" as scientifically plausible based upon reliable evidence. *See id.* at 1211. And this court has recognized that deficiencies in a particular differential diagnosis can support a district court's decision to exclude expert testimony. *See id.* at 1212.

Ronwin v. Bayer Corp., No. 08-8089, 332 Fed. Appx. 508, 514, n.6, 2009 WL 1678198, 5 (10th Cir. June 17, 2009); *see Goebel v. Denver & Rio Grande W. R. Co.*, 346 F.3d 987, 998 (10th Cir. 2003) (stating, "a reliable differential diagnosis is admissible in this circuit given a valid showing of general causation").

concludes that, besides not properly "ruling in" subpotent tacrolimus as the cause of Blanca's rejection, none of the medical experts sufficiently showed valid reasons for ruling out the most likely cause of the kind of catastrophic rejection Blanca suffered, which according to Dr. Alexander and Dr. Wong, is non-adherence. *See Ronwin v. Bayer Corp.*, No. 08-8089, 332 Fed. Appx. 508, 514, n.6, 2009 WL 1678198, 5 (10th Cir. June 17, 2009)

Further, because Blanca's blood levels were not tested for a month before her renal- failure symptoms began or before Dr. Brandt decreased her tacrolimus dosage by half, the doctors could only speculate about what her tacrolimus levels may have been until May 17, when they knew she was already experiencing a "catastophic" rejection. As Dr. Wong testified, without evidence to support either that the tacrolimus suspension was subpotent or that Blanca was nonadherent in taking her medication, "we just know that the rejection happened. . . . .[W]e can guess for a long time what might have caused it." Doc. 203, Ex. 1 at 10.

The Court concludes that Dr. Wong's, Dr. Alexander's and Dr. Morganstern's opinions regarding the potency or the correct compounding of the tacrolimus BioScrip dispensed and its alleged causal connection to Blanca's transplant rejection are based on speculation and inaccurate assumptions and are not supported by scientific or other medical evidence. They are, therefore unreliable and inadmissible under FED. R. EVID. 702 and *Daubert*.

IT IS ORDERED that BioScrip's *Daubert Motion to Exclude Certain Proposed Testimony of Craig Wong, M.D., Bruce Morgenstern, M.D., and Loyd Alexander, M.D.* [Doc. 175] is GRANTED and that neither Dr. Wong, Dr. Alexander, nor Dr. Morganstern shall be permitted to testify regarding the potency, adequacy, or compounding of the tacrolimus suspension BioScrip dispensed or that a subpotency or inadequacy of BioScrip's suspension either caused low levels of tacrolimus in Blanca's system or was a cause of Blanca's transplant rejection.

Robert Hayes Scott

ROBERT HAYES SCOTT
UNITED STATES MAGISTRATE JUDGE
Presiding by Consent